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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/736,267	10/24/1996	KJELL G. E. BACKSTROM	06275/004001	3709

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EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1653	51

DATE MAILED: 10/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/736,267	BACKSTROM ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

#119

4)☒ Claim(s) *1,3-10,12-16,21,22,26,27,29-32,50-87,89-97 and 101-118* is/are pending in the application.

4a) Of the above claim(s) *28,56,61-77,79 and 88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,21,22,26,27,29,30,32,50-55,57-60,78,80-87,89-97 and 102* is/are rejected.

7)☒ Claim(s) *3,5-10,12-16,31,101 and 103-118* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *49* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Pursuant to the directives of paper No. 50 (filed 7/19/02), claim 2 has been cancelled, and claims 1, 21, 30, 56, 59, 71, 89, 94 amended. Claims 1, 3-10, 12-16, 21, 22, 26, 27, 29-32, 50-87, 89-97, 101-118 remain pending.

The following claims are now rejoined with the elected group: 21, 22, 26, 27, 29, 30, 32, 50-55, 57-60, 78, 80-87, 89-97. The following claims are not rejoined, and remain withdrawn: 28, 56, 61-77, 79 and 88.

- Claim 56 is not rejoined because it permits the presence of any phospholipid, and not just those that are recited in claim 1
- Claims 61-77 are not rejoined, because these are contained within Group II, as defined by the restriction requirement mailed 12/30/99.
- Claim 79 is not rejoined, because it is not subgeneric to claim 78.
- Claims 28 and 88 are not rejoined, because there is no antecedent basis for the "enhancer".

Claims 1, 3-10, 12-16, 21, 22, 26, 27, 29-32, 50-55, 57-60, 78, 80-87, 89-97, 101, 102, 103-118 are examined in this Office action.

*

- Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,518,998 or

5,518,998 C1. Although the conflicting claims are not identical, they are not patentably distinct from each other; there is overlap of the claimed subject matter.

- Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,747,445. Although the conflicting claims are not identical, they are not patentably distinct from each other; there is overlap of the claimed subject matter.

- Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,165,976. Although the conflicting claims are not identical, they are not patentably distinct from each other; there is overlap of the claimed subject matter.

- Claim 21 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,830,853. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of '853 is drawn to a method of treating diabetes (or other insulin-deficient disease) by administering insulin by means of a dry powder inhalation device. Claim 21 of the instant application does not mention insulin or diabetes or a dry powder inhalation device; claim 21 is not even directed to treatment of a disease. However, it is clear from a reading of the specification that insulin is the most preferred peptide to administer; a person practicing the '853 invention would be systemically administering the insulin to the same extent as the practioner of the instant application. The difference is that the '853 invention requires therapeutic success as a consequence of the administration; the instant claims only require that administration be achieved.

- Claim 102 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,004,574. Although the conflicting claims are not identical, they are not patentably distinct from each other; there is overlap of the claimed subject matter.

- Claim 78 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,436,902. Although the conflicting claims are not identical, they are not patentably distinct from each other; there is overlap of the claimed subject matter.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application . See 37 CFR 1.78(d)

*

Claims 4, 21, 22, 26, 27, 29, 30, 32, 50-55, 57-60, 78, 80-87, 89-97 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In claim 4, the term "biologically active" renders the claim indefinite as to the manifestations of that activity.

- In claim 4, the term "analog" renders the claim indefinite as to structure and activity.

- In claim 21, "said patient" lacks antecedent basis.

- Claim 21 is indefinite as to the process steps and enpoint. For example, if the patient were to inhale just 1 milliliter of air, would that be sufficient? How does one distinguish the patient who has undertaken the steps necessary to achieve systemic administration, from the patient who has not? One option would be to recite that the patient inhales the composition *for a time and under conditions effective for the polypeptide to be absorbed through the epithelial cells of the lower respiratory tract.*

  Another option would be to recite that the patient inhales the composition *for a time and under conditions effective for the polypeptide to be conveyed to the bloodstream of the patient.*

- In each of claims 27, 81 and 105, the term "biologically active" renders the claim

indefinite as to the manifestations of that activity.

- In each of claims 27, 81 and 105, the term "analog" renders the claim indefinite as to structure and activity.

❄

Document 8007820 (Swedish patent) was stricken from the IDS because it was not recieved.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800